

### **REMARKS**

Claims 1-3, 19-20, 47-53, and 67-70 are pending in the instant application. Withdrawn claims 8-18, 21-42, 54-66 and 71 were canceled as they are directed to non-elected subject matter. Claims 1, 47, 51-53, 68, 70, 72-80 and 83-86 are allowable. In order to simplify the issues, and to pursue preferred embodiments of the invention, and to present the case for allowance and minimize issues for appeal, claims 48-49 were cancelled without prejudice to the prosecution thereof in a subsequent application, and claims 50, 69, 81, and 82 were amended to cancel contested subject matter without prejudice to the prosecution thereof in a subsequent application. In addition, newly added dependent claims 87-89 are directed embodiments of the polypeptides of the present invention that comprise labels, etc. that are encompassed within the scope the instant and original claims; these newly added claims contain the same limitations as supported in claims 50, 69, 81, and 82. No new matter was added by these amendments. Applicant believes the case is in condition for allowance.

#### **A. Priority Issues from January 29, 2004 Office Action (OA)**

##### **(1) Priority**

Applicant has as not acquiesced to the Office's reasoning or position as applied to the priority and sufficiency of disclosure in the 60/169,049 priority application (99-93P1; filed 12/03/99) particularly as applied to various receptor complexes, such as heterodimeric and homodimeric receptor complexes, as briefly noted in Applicant's response dated September 23, 2002. Without prejudice, Applicant has decided to pursue the subject matter in a subsequent application.

#### **C. Rejections Addressed from January 29, 2004 Office Action (OA)**

##### **(1) Rejection of claims 50, 69 and 81 and 82 under 35 U.S.C. § 112, first paragraph (new matter)**

Claims 50, 69 and 81 and 82 were rejected under 35 USC §112, first paragraph because the Office believes that the claims contain "new matter" in the form of "written description [for] a polypeptide or receptor complex that further comprises a biotin/avidin label,

radionuclide, an enzyme, a substrate, a cofactor, an inhibitor, a fluorescent marker, a chemiluminescent marker, or a cytotoxic molecule. Solely in order to expedite prosecution and to allow certain embodiments of the invention to issue, Applicant has amended claims 50, 69, 81, and 82 so as to include the following: “affinity tag, chemical moiety, toxin, label, or an immunoglobulin Fc domain.” Support for “affinity tag, chemical moiety, toxin, label” is found in original claim 50 as filed, and support for “an immunoglobulin Fc domain” is found in the specification on page 7, lines 3-7; page 18, lines 5-7, page 61, lines 1-27 and particularly lines 1-7; page 64, line 3, to page 65, line 4; and in Examples 1, 10, 11, 15, and 16. Applicant is pointing to these sections of the specification to emphasize that the zcytor16 polypeptides of the present invention are indeed described at length with the addition of an immunoglobulin Fc domain, in fact Applicant has produced such fusion proteins, and has demonstrated that they antagonize IL-22 (IL-TIF). No new matter was added by this amendment. Such polypeptides described in claims 50, 69 and 81 and 82, and as may apply to newly added claims 86-89 since they contain the same limitations, are indeed supported in the specification and are not new matter. As applied to the instant claim 50, 69, 81 and 82, and as may apply to newly added claims 86-89, this rejection is moot. Consequently the rejection of claims 50, 69, 81 and 82, and as may apply to newly added claims 86-89, under 35 USC §112, first paragraph should be properly withdrawn.

Although Applicant has amended claims to expedite prosecution and allowance of the case, Applicant has as not acquiesced to the Office’s reasoning or position on “new matter” and respectfully traverses the rejection, as applied to polypeptides of the present invention further comprising a biotin/avidin label, radionuclide, an enzyme, a substrate, a cofactor, an inhibitor, a fluorescent marker, a chemiluminescent marker, or a cytotoxic molecule as was presented in the response dated September 23, 2002. Without prejudice, Applicant will pursue the subject matter in a subsequent application.

(2) Rejection of claims 48-49 under 35 U.S.C. § 102(e)

Claims 48 and 49 remain rejected under 35 U.S.C. §102(e) as being anticipated by Agarwal et al. (WO 01/198342, December 27, 2001). Claims 48 and 49 were canceled,

rendering this rejection moot. Consequently, Applicant requests that the rejection of claims 47-50 be properly withdrawn.

Although Applicant has canceled claims 48 and 49 to expedite prosecution, Applicant respectfully maintains that the Agarwal et al. reference is not available as prior art under 35 U.S.C. §102(e) for the purposes maintained by the Office. Applicant has as not acquiesced to the Office's reasoning or position on "priority" or 35 USC §102(e) matters and respectfully traverses the rejection, as applied to the priority and sufficiency of disclosure in the 60/169,049 priority application (99-93P1; filed December 3, 1999) particularly as applied to various receptor complexes, such as heterodimeric and homodimeric receptor complexes, as briefly noted in Applicant's response dated September 23, 2002.

Applicant further submits for the record the priority documents of Agarwal et al. (WO 01/198342, December 27, 2001) reference cited by the Office and on which date the Office relies for its rejection (June 22, 2000), namely US 60/213,156 (filed 06/22/00), and US 60/213,161 (copies enclosed). Applicant further submits that said Agarwal priority documents do not disclose essential elements of Applicants invention prior to the disclosure by Applicant, such as the full length or mature zcytor16 sequences (e.g., SEQ ID NO:2, SEQ ID NO:2 from amino acid 22-231) as filed in the 60/169,049 priority application (99-93P1; filed December 3, 1999; e.g., see specification page 2, paragraph 4, and SEQ ID NO:2), and hence cannot be considered prior art under 35 USC §102(e). Under 35 U.S.C. 102, for a prior reference to anticipate an invention, every element of the claim must be included in a single reference. Since priority documents of Agarwal lack all necessary elements of the invention, they cannot anticipate the invention.

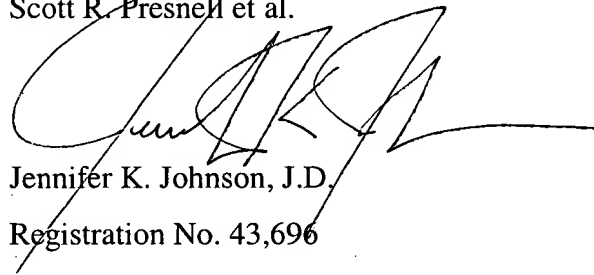
The Office relies on Agarwal's SEQ ID NO:40 and SEQ ID NO:42 (WO 01/198342, December 27, 2001), but these sequences are not are not identical to Applicants full length or mature zcytor16 sequences (e.g., SEQ ID NO:2, SEQ ID NO:2 from amino acid 22-231), and hence cannot be considered relevant prior art. In addition, Agarwal's SEQ ID NO:42 was not included in Agarwal's priority documents. Moreover, Agarwal's SEQ ID NO:41 (WO 01/198342, December 27, 2001), which the Office submits is identical to SEQ ID NO:2 (however it does not describe any mature sequence of SEQ ID NO:2 from amino acid 22-231),

was not included in Agarwal's priority documents, and was not disclosed by Agarwal until the international filing date of June 22, 2001, which was *over six months after* the *all* disclosures by Applicant in all provisional applications and the instant application under consideration: priority application 60/169,049 (99-93P1; filed December 3, 1999); priority application 60/232,219 (99-93P2; filed September 12, 2000); priority application 60/244,610 (99-93P3; filed October 31, 2000); and US Application (09/728,911; filed December 01, 2000). Consequently, the Agarwal reference (WO 01/198342, December 27, 2001) cannot be considered prior art under 35 USC §102(e). Consequently, this rejection should be properly withdrawn.

Early reconsideration and allowance of the pending claims is respectfully requested. If the Patent Examiner believes that a telephone interview would expedite prosecution of this patent application, please call the undersigned at (206) 442-6676.

Respectfully Submitted,

Scott R. Presnell et al.

A large, stylized handwritten signature in black ink, appearing to read 'Jennifer K. Johnson', is written over the typed name and registration number.

Jennifer K. Johnson, J.D.

Registration No. 43,696

Enclosures:

Amendment Fee Transmittal (in duplicate)

Copy of Agarwal Priority Document (US 60/213,156)

Copy of Agarwal Priority Document (US 60/213,161)

Notice of Appeal

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